**AS9100D Master Internal Audit Checklist**

**Developed by: Bill Houser**

**NOTE: Proprietary Eagle Force, Inc. Information**

**Process/Function Audited \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_**

**Auditor(s) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

## Note: The following questions are to be answered by the internal auditors with a “yes” or “no” followed by the evidence (documentation, records, observations, questioning, etc. supporting the answer)

**4 Context of the organization**

**4.1 Understanding the organization and its context**

Has the organization determined the external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of the quality management system?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization monitor and review information about these external and internal issues?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**4.2 Understanding the needs and expectations of interested parties**

Has the organization determined:

1. the interested parties that are relevant to the quality management system;
2. the requirements of these interested parties that are relevant to the quality management system?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization monitor and review information about these interested parties and their relevant requirements?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**4.3 Determining the scope of the quality management system**

Has the organization determined the boundaries and applicability of the quality management system to establish its scope?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

When determining this scope, did the organization consider:

1. the external and internal issues referred to in 4.1;
2. the requirements of relevant interested parties referred to in 4.2;
3. the products and services of the organization?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization apply all the requirements of ISO 9001:2015 if they are applicable within the scope of the quality management system?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Is the scope of the quality management system available and maintained as documented information?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the scope state the types of products and services covered, and provide justification for any requirement of ISO 9001:2015 that the organization determines is not applicable to the scope of its quality management system?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**4.4 Quality management system and its processes**

**4.4.1**

Has the organization established, implemented, maintained and continually improved the quality management system, including the processes needed and their interactions, in accordance with the requirements of ISO 9001: 2015?

***Does the organization’s quality management system also address customer and applicable statutory and regulatory quality management system requirements? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Has the organization determined the processes needed for the quality management system and their application throughout the organization, and:

1. determined the inputs required and the outputs expected from these processes;
2. determined the sequence and interaction of these processes;
3. determined and applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
4. determined the resources needed for these processes and ensure their availability;
5. assigned the responsibilities and authorities for these processes;
6. addressed the risks and opportunities as determined in accordance with the requirements of 6.1;
7. evaluated these processes and implement any changes needed to ensure that these processes achieve their intended results;
8. improved the processes and the quality management system?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**4.4.2**

As necessary, does the organization:

1. maintain documented information to support the operation of its processes;
2. retain documented information to have confidence that the processes are being carried out as planned?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Has the organization established and maintained documented information that includes:***

* ***a general description of relevant interested parties (see 4.2 a);***
* ***the scope of the quality management system, including boundaries and applicability (see 4.3); a description of the processes needed for the quality management system and their application throughout the organization;***
* ***the sequence and interaction of these processes;***
* ***assignment of the responsibilities and authorities for these processes? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**5 Leadership**

**5.1 Leadership and commitment**

**5.1.1 General**

Does top management demonstrate leadership and commitment with respect to the quality management system by:

1. taking accountability for the effectiveness of the quality management system;
2. ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;
3. ensuring the integration of the quality management system requirements into the organization’s business processes;
4. promoting the use of the process approach and risk-based thinking;
5. ensuring that the resources needed for the quality management system are available;
6. communicating the importance of effective quality management and of conforming to the quality management system requirements;
7. ensuring that the quality management system achieves its intended results;
8. engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
9. promoting improvement;
10. supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**5.1.2 Customer focus**

Does top management demonstrate leadership and commitment with respect to customer focus by ensuring that:

1. customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
2. risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
3. focus on enhancing customer satisfaction is maintained;
4. ***product and service conformity and on-time delivery performance are measured and appropriate action is taken if planned results are not, or will not be, achieved? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**5.2 Policy**

**5.2.1 Establishing the quality policy**

Has top management established, implemented and maintained a quality policy that:

1. is appropriate to the purpose and context of the organization and supports its strategic direction;
2. provides a framework for setting quality objectives;
3. includes a commitment to satisfy applicable requirements;
4. includes a commitment to continual improvement of the quality management system?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**5.2.2 Communicating the quality policy**

Is quality policy:

1. available and maintained as documented information;
2. communicated, understood and applied within the organization;
3. available to relevant interested parties, as appropriate?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**5.3 Organizational roles, responsibilities and authorities**

Has top management ensured that responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Has top management assigned responsibility and authority for:

1. ensuring that the quality management system conforms to the requirements of ISO 9001:2015;
2. ensuring that the processes are delivering their intended outputs;
3. reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;
4. ensuring the promotion of customer focus throughout the organization;
5. ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Has top management appointed a specific member of the management, identified as the management representative, who has the responsibility and authority for oversight of the above requirements? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Does the management representative have the organizational freedom and unrestricted access to top management to resolve quality management issues? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**6 Planning**

**6.1 Actions to address risks and opportunities**

**6.1.1**

When planning for the quality management system, does the organization consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

1. give assurance that the quality management system can achieve its intended result(s);
2. enhance desirable effects;
3. prevent, or reduce, undesired effects;
4. achieve improvement?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**6.1.2**

Does the organization plan:

1. actions to address these risks and opportunities;
2. how to:
3. integrate and implement the actions into its quality management system processes (see 4.4);
4. evaluate the effectiveness of these actions?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Are actions taken to address risks and opportunities proportionate to the potential impact on the conformity of products and services?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**6.2 Quality objectives and planning to achieve them**

**6.2.1**

Has the organization established quality objectives at relevant functions, levels and processes needed for the quality management system?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Are the quality objectives:

1. consistent with the quality policy;
2. measurable;
3. taking applicable requirements into account;
4. relevant to conformity of products and services and to enhancement of customer satisfaction;
5. monitored;
6. communicated;
7. updated as appropriate?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization maintain documented information on the quality objectives?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**6.2.2**

When planning how to achieve its quality objectives, does the organization determine:

1. what will be done;
2. what resources will be required;
3. who will be responsible;
4. when it will be completed;
5. how the results will be evaluated?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**6.3 Planning of changes**

When the organization determines the need for changes to the quality management system, are the changes carried out in a planned manner?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization consider:

1. the purpose of the changes and their potential consequences;
2. the integrity of the quality management system;
3. the availability of resources;
4. the allocation or reallocation of responsibilities and authorities?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**7 Support**

**7.1 Resources**

**7.1.1 General**

Does the organization determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization consider:

1. the capabilities of, and constraints on, existing internal resources;
2. what needs to be obtained from external providers?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**7.1.2 People**

Does the organization determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**7.1.3 Infrastructure**

Does the organization determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**7.1.4 Environment for the operation of processes**

Does the organization determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**7.1.5 Monitoring and measuring resources**

**7.1.5.1 General**

Does the organization determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization ensure that the resources provided:

1. are suitable for the specific type of monitoring and measurement activities being undertaken;
2. are maintained to ensure their continuing fitness for their purpose?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**7.1.5.2 Measurement traceability**

When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, is measuring equipment:

1. calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, is the basis used for calibration or verification retained as documented information;
2. identified in order to determine their status;
3. safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Has a process for the recall of monitoring and measuring equipment requiring calibration or verification been established, implemented, and maintained? (AS9100D)***

***Is a register maintained of the monitoring and measuring equipment, and does the register include the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Is calibration or verification of monitoring and measuring equipment carried out under suitable environmental conditions (see 7.1.4). (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and do they take appropriate action as necessary?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**7.1.6 Organizational knowledge**

Does the organization determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Is this knowledge maintained and be made available to the extent necessary?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

When addressing changing needs and trends, does the organization consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**7.2 Competence**

Does the organization:

1. determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;
2. ensure that these persons are competent on the basis of appropriate education, training, or experience;
3. where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
4. retain appropriate documented information as evidence of competence?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**7.3 Awareness**

Does the organization ensure that persons doing work under the organization’s control are aware of:

1. the quality policy;
2. relevant quality objectives;
3. their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
4. the implications of not conforming with the quality management system requirements;
5. ***relevant quality management system documented information and changes thereto;***
6. ***their contribution to product or service conformity;***
7. ***their contribution to product safety;***
8. ***the importance of ethical behavior? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**7.4 Communication**

Does the organization determine the internal and external communications relevant to the quality management system, including:

1. on what it will communicate;
2. when to communicate;
3. with whom to communicate;
4. how to communicate;
5. who communicates?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**7.5 Documented information**

**7.5.1 General**

Does the organization’s quality management system include:

1. documented information required by ISO 9001:2015;
2. documented information determined by the organization as being necessary for the effectiveness of the quality management system?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**7.5.2 Creating and updating**

When creating and updating documented information, does the organization ensure appropriate:

1. identification and description (e.g. a title, date, author, or reference number);
2. format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
3. review and approval for suitability and adequacy?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**7.5.3 Control of documented information**

**7.5.3.1**

Is documented information required by the quality management system and by ISO 9001:2015 controlled to ensure:

1. it is available and suitable for use, where and when it is needed;
2. it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**7.5.3.2**

For the control of documented information, does the organization address the following activities, as applicable:

1. distribution, access, retrieval and use;
2. storage and preservation, including preservation of legibility;
3. control of changes (e.g. version control);
4. retention and disposition;
5. ***prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose*? *(AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Is documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system identified as appropriate, and controlled?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Is documented information retained as evidence of conformity protected from unintended alterations?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***When documented information is managed electronically, are data protection processes defined (e.g., protection from loss, unauthorized changes, unintended alteration, corruption, physical damage)? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8 Operation**

**8.1 Operational planning and control**

Does the organization plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:

1. determining the requirements for the products and services;
2. establishing criteria for:

1) the processes;

2) the acceptance of products and services;

1. determining the resources needed to achieve conformity to the product and service requirements, ***and to meet on-time delivery of products and services***; ***(AS9100D)***
2. implementing control of the processes in accordance with the criteria;
3. determining, maintaining and retaining documented information to the extent necessary:
4. to have confidence that the processes have been carried out as

planned;

1. to demonstrate the conformity of products and services to their

requirements;

1. ***determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;***
2. ***engaging representatives of affected organization functions for operational planning and control;***
3. ***determining the process and resources to support the use and maintenance of the products and services;***
4. ***determining the products and services to be obtained from external providers;***
5. ***establishing the controls needed to prevent the delivery of nonconforming products and services to the customer? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***As appropriate to the organization, customer requirements, and products and services, is product and service provision planned and managed in a structured and controlled manner, including scheduled events performed in a planned sequence to meet requirements at acceptable risk, within resource and schedule constraints? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Is the output of this planning suitable for the organization’s operations?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization ensure that outsourced processes are controlled (see 8.4)?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Has a process been established, implemented, and maintained to plan and control the temporary or permanent transfer of work, to ensure the continuing conformity of the work to requirements, and does the process ensure that work transfer impacts and risks are managed? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***8.1.1 Operational Risk Management***

***Has a process been planned, implemented and controlled for managing operational risks to the achievement of applicable requirements, that includes as appropriate to the organization and the products and services:***

1. ***assignment of responsibilities for operational risk management;***
2. ***definition of risk assessment criteria (e.g., likelihood, consequences, risk acceptance);***
3. ***identification, assessment, and communication of risks throughout operations;***
4. ***identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria;***
5. ***acceptance of risks remaining after implementation of mitigating actions? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***8.1.2 Configuration Management***

***Has a process been planned, implemented, and controlled for configuration management as appropriate to the organization and its products and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle, and does this process:***

1. ***control product identity and traceability to requirements, including the implementation of identified changes;***
2. ***ensure that the documented information (e.g., requirements, design, verification, validation and acceptance documentation) is consistent with the actual attributes of the products and services? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***8.1.3 Product Safety***

***Have the processes needed to assure product safety during the entire product life cycle been planned, implemented and controlled, as appropriate to the organization and the product? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***8.1.4 Prevention of Counterfeit Parts***

***Have processes, appropriate to the organization and the product been planned, developed and controlled for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8.2 Requirements for products and services**

**8.2.1 Customer communication**

Does communication with customers include:

a) providing information relating to products and services;

b) handling inquiries, contracts or orders, including changes;

c) obtaining customer feedback relating to products and services, including customer complaints;

d) handling or controlling customer property;

e) establishing specific requirements for contingency actions, when relevant?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8.2.2 Determining the requirements for products and services**

When determining the requirements for the products and services to be offered to customers, does the organization ensure that:

1. the requirements for the products and services are defined, including:

1) any applicable statutory and regulatory requirements;

2) those considered necessary by the organization;

1. the organization can meet the claims for the products and services it offers;
2. ***special requirements of the products and services are determined;***
3. ***operational risks (e.g., new technology, ability and capacity to provide, short delivery time frame) have been identified? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8.2.3 Review of the requirements for products and services**

**8.2.3.1**

Does the organization ensure that it has the ability to meet the requirements for products and services to be offered to customers?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization conduct a review before committing to supply products and services to a customer, that includes:

1. requirements specified by the customer, including the requirements for delivery and post delivery activities;
2. requirements not stated by the customer, but necessary for the specified or intended use, when known;
3. requirements specified by the organization;
4. statutory and regulatory requirements applicable to the products and services;
5. contract or order requirements differing from those previously expressed?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Is this review coordinated with applicable functions of the organization? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***If upon review it is determined that some customer requirements cannot be met or can only partially be met, are mutually acceptable requirements negotiated with the customer? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization ensure that contract or order requirements differing from those previously defined are resolved?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Are the customer’s requirements confirmed by the organization before acceptance when the customer does not provide a documented statement of their requirements.

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8.2.3.2**

Does the organization retain documented information, as applicable:

1. on the results of the review;
2. on any new requirements for the products and services?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8.2.4 Changes to requirements for products and services**

Does the organization ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8.3 Design and development of products and services**

**8.3.1 General**

Has the organization established, implemented and maintained a design and development process that is appropriate to ensure the subsequent provision of products and services?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8.3.2 Design and development planning**

In determining the stages and controls for design and development, does the organization consider:

1. the nature, duration and complexity of the design and development activities;
2. the required process stages, including applicable design and development reviews;
3. the required design and development verification and validation activities;
4. the responsibilities and authorities involved in the design and development process;
5. the internal and external resource needs for the design and development of products and services;
6. the need to control interfaces between persons involved in the design and development process;
7. the need for involvement of customers and users in the design and development process;
8. the requirements for subsequent provision of products and services;
9. the level of control expected for the design and development process by customers and other relevant interested parties;
10. the documented information needed to demonstrate that design and development requirements have been met?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***When appropriate, are design and development efforts divided into distinct activities and, for each activity, are the tasks, necessary resources, responsibilities, design content, and inputs and outputs defined? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Does design and development planning consider the ability to provide, verify, test and maintain products and services (reference output of 8.1 a)? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8.3.3 Design and development inputs**

Does the organization determine the requirements essential for the specific types of products and services to be designed and developed, and consider:

1. functional and performance requirements;
2. information derived from previous similar design and development activities;
3. statutory and regulatory requirements;
4. standards or codes of practice that the organization has committed to implement;
5. potential consequences of failure due to the nature of the products and services;
6. ***when applicable, the potential consequences of obsolescence (e.g., materials, processes, components, equipment, products)? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Are inputs adequate for design and development purposes, complete and unambiguous, and are conflicting design and development inputs resolved?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization retain documented information on design and development inputs.

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8.3.4 Design and development controls**

Does the organization apply controls to the design and development process to ensure that:

1. the results to be achieved are defined;
2. reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
3. verification activities are conducted to ensure that the design and development outputs meet the input requirements;
4. validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;
5. any necessary actions are taken on problems determined during the reviews, or verification and validation activities;
6. documented information of these activities is retained;
7. ***progression to the next stage is authorized? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Do participants in design and development reviews include representatives of functions concerned with the design and development stage(s) being reviewed? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***8.3.4.1 When tests are necessary for verification and validation, are these tests planned, controlled, reviewed, and documented to ensure and prove the following:***

1. ***test plans or specifications identify the test item being tested and the resources being used, define test objectives and conditions, parameters to be recorded and relevant acceptance criteria;***
2. ***test procedures describe the test methods to be used, how to perform the test, and how to record the results;***
3. ***the correct configuration of the test item is submitted for the test;***
4. ***the requirements of the test plan and the test procedures are observed;***
5. ***the acceptance criteria are met? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Are monitoring and measuring devices used for testing controlled as defined in clause 7.1.5? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***At the completion of design and development, does the organization ensure that reports, calculations, test results, etc., are able to demonstrate that the design for the product or service meets the specification requirements for all identified operational conditions? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8.3.5 Design and development outputs**

Does the organization ensure that design and development outputs:

1. meet the input requirements;
2. are adequate for the subsequent processes for the provision of products and services;
3. include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
4. specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision;
5. ***specify, as applicable, any critical items, including any key characteristics, and specific actions to be taken for these items;***
6. ***are approved by authorized person(s) prior to release? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Is the data required to allow the product to be identified, manufactured, verified, used, and maintained been defined? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Is documented information retained on design and development outputs?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8.3.6 Design and development changes**

Does the organization identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Has a process been implemented with criteria for notifying its customer, prior to implementation, about changes that affect customer requirements? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Is documented information retained on:

1. design and development changes;
2. the results of reviews;
3. the authorization of the changes;
4. the actions taken to prevent adverse impacts?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Are design and development changes controlled in accordance with the configuration management process requirements? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8.4 Control of externally provided processes, products and services**

**8.4.1 General**

Does the organization ensure that externally provided processes, products and services conform to requirements?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Does the organization recognize responsibility for conformity of all externally provided processes, products, and services, including from sources defined by the customer? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***When required, are customer-designated or approved external providers, including process sources (e.g., special processes), used? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Are risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers, identified and managed? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Is it required that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization determine the controls to be applied to externally provided processes, products and services when:

1. products and services from external providers are intended for incorporation into the organization’s own products and services;
2. products and services are provided directly to the customer(s) by external providers on behalf of the organization;
3. a process, or part of a process, is provided by an external provider as a result of a decision by the organization?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements, and does the organization retain documented information of these activities and any necessary actions arising from the evaluations?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***8.4.1.1 Has the organization:***

1. ***defined the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status;***
2. ***maintained a register of its external providers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family);***
3. ***periodically reviewed external provider performance including process, product and service conformity, and ontime delivery performance;***
4. ***defined the necessary actions to take when dealing with external providers that do not meet requirements;***
5. ***defined the requirements for controlling documented information created by and/or retained by external providers? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8.4.2 Type and extent of control**

Does the organization ensure that externally provided processes, products and services do not adversely affect the organization’s ability to consistently deliver conforming products and services to its customers?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization:

1. ensure that externally provided processes remain within the control of its quality management system;
2. define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
3. take into consideration:

1) the potential impact of the externally provided processes, products and

services on the organization’s ability to consistently meet customer and

applicable statutory and regulatory requirements;

2) the effectiveness of the controls applied by the external provider;

1. ***the results of the periodic review of external provider performance (see 8.4.1.1 c); (AS9100D)***
2. determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Are verification activities of externally provided processes, products, and services performed according to the risks identified, and, as applicable, do these include inspection or periodic testing when there is high risk of nonconformities including counterfeit parts? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***When externally provided product is released for production use pending completion of all required verification activities, is it identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***When the organization delegates verification activities to the external provider, are the scope and requirements for delegation defined and a register of delegations maintained? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Does the organization periodically monitor the external provider’s delegated verification activities? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***When external provider test reports are used to verify externally provided products, is there a process to evaluate the data in the test reports to confirm that the product meets requirements? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***When a customer or organization has identified raw material as a significant operational risk (e.g., critical items), is a process implemented to validate the accuracy of test reports? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8.4.3 Information for external providers**

Does the organization ensure the adequacy of requirements prior to their communication to the external provider.

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization communicate to external providers its requirements for:

1. the processes, products and services to be provided; ***including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions); (AS9100D)***
2. the approval of:

1) products and services;

2) methods, processes and equipment;

3) the release of products and services;

1. competence, including any required qualification of persons;
2. the external providers’ interactions with the organization;
3. control and monitoring of the external providers’ performance to be applied by the organization;
4. verification or validation activities that the organization, or its customer, intends to perform at the external providers’ premises?
5. ***design and development control;***
6. ***special requirements, critical items, or key characteristics;***
7. ***test, inspection, and verification (including production process verification);***
8. ***the use of statistical techniques for product acceptance and related instructions for acceptance by the organization;***
9. ***the need to:***

* ***implement a quality management system;***
* ***use customer-designated or approved external providers, including process sources (e.g., special processes);***
* ***notify the organization of nonconforming processes, products, or services and obtain approval for their disposition;***
* ***prevent the use of counterfeit parts (see 8.1.4);***
* ***notify the organization of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain the organization’s approval;***
* ***flow down to external providers applicable requirements including customer requirements;***
* ***provide test specimens for design approval, inspection/verification, investigation, or auditing;***
* ***retain documented information, including retention periods and disposition requirements;***

1. ***the right of access by the organization, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain;***
2. ***ensuring that persons are aware of:***

* ***their contribution to product or service conformity;***
* ***their contribution to product safety;***
* ***the importance of ethical behavior? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8.5 Production and service provision**

**8.5.1 Control of production and service provision**

Has the organization implemented production and service provision under controlled conditions that include, as applicable:

1. the availability of documented information that defines:

1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;

2) the results to be achieved;

1. the availability and use of suitable monitoring and measuring resources;
2. the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;

* ***ensuring that documented information for monitoring and measurement activity for product acceptance includes:***
* ***criteria for acceptance and rejection; (AS9100D)***
* ***where in the sequence verification operations are to be performed;***
* ***measurement results to be retained (at a minimum an indication of acceptance or rejection);***
* ***any specific monitoring and measurement equipment required and instructions associated with their use;***
* ***ensuring that when sampling is used as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability). (AS9100D)***

1. the use of suitable infrastructure and environment for the operation of processes;
2. the appointment of competent persons, including any required qualification;
3. the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
4. the implementation of actions to prevent human error;
5. the implementation of release, delivery and post-delivery activities;
6. ***the establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);***
7. ***the accountability for all products during production (e.g., parts quantities, split orders, nonconforming product);***
8. ***the control and monitoring of identified critical items, including key characteristics, in accordance with established processes;***
9. ***the determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);***
10. ***the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;***
11. ***the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;***
12. ***the provision for the prevention, detection, and removal of foreign objects;***
13. ***the control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements (see 7.1.3);***
14. ***the identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***8.5.1.1 Control of Equipment, Tools, and Software Programs***

***Are equipment, tools, and software programs used to automate, control, monitor, or measure production processes validated prior to final release for production and are they maintained? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Are storage requirements defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***8.5.1.2 Validation and Control of Special Processes***

***For processes where the resulting output cannot be verified by subsequent monitoring or measurement, has the organization established arrangements for these processes including, as applicable:***

1. ***definition of criteria for the review and approval of the processes;***
2. ***determination of conditions to maintain the approval;***
3. ***approval of facilities and equipment;***
4. ***qualification of persons;***
5. ***use of specific methods and procedures for implementation and monitoring the processes;***
6. ***requirements for documented information to be retained? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***8.5.1.3 Production Process Verification***

***Has the organization implemented production process verification activities to ensure the production process is able to produce products that meet requirements? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Does the organization use a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation, and tooling are able to produce parts and assemblies that meet requirements, and is this activity repeated when changes occur that invalidate the original results (e.g., engineering changes, production process changes, tooling changes)? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Does the organization retain documented information on the results of production process verification? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8.5.2 Identification and traceability**

Does the organization use suitable means to identify outputs when it is necessary to ensure the conformity of products and services?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Does the organization maintain the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***If acceptance authority media are used (e.g., stamps, electronic signatures, passwords), are controls for the media established? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization control the unique identification of the outputs when traceability is a requirement, and is documented information necessary to enable traceability retained?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8.5.3 Property belonging to customers or external providers**

Does the organization exercise care with property belonging to customers or external providers while it is under the organization’s control or being used by the organization?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization identify, verify, protect and safeguard customers’ or external providers’ property provided for use or incorporation into the products and services?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, does the organization report this to the customer or external provider and retain documented information on what has occurred?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8.5.4 Preservation**

Does the organization preserve the outputs during production and service provision to the extent necessary to ensure conformity to requirements?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***When applicable in accordance with specifications and applicable statutory and regulatory requirements, does preservation of outputs also include provisions for:***

1. ***cleaning;***
2. ***prevention, detection, and removal of foreign objects;***
3. ***special handling and storage for sensitive products;***
4. ***marking and labeling, including safety warnings and cautions;***
5. ***shelf life control and stock rotation;***
6. ***special handling and storage for hazardous materials?***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8.5.5 Post-delivery activities**

Does the organization meet any requirements for post-delivery activities associated with the products and services, and in determining the extent of post-delivery activities is the following considered:

1. statutory and regulatory requirements;
2. the potential undesired consequences associated with its products and services;
3. the nature, use and intended lifetime of its products and services;
4. customer requirements;
5. customer feedback;
6. ***collection and analysis of in-service data (e.g., performance, reliability, lessons learned);***
7. ***control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul;***
8. ***controls required for work undertaken external to the organization (e.g., off-site work);***
9. ***product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence)?***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***When problems are detected after delivery, does the organization take appropriate action including investigation and reporting?***

**8.5.6 Control of changes**

Does the organization review and control production or service changes, to the extent necessary to ensure continuing conformity with requirements?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Are persons authorized to approve production or service provision changes identified? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Is documented information retained describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8.6 Release of products and services**

Has the organization implemented planned arrangements, at appropriate stages, to verify that the product and service requirements have been met?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the release of products and services to the customer not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer, and is documented information retained on the release of products and services?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the documented information include:

1. evidence of conformity with the acceptance criteria;
2. traceability to the person(s) authorizing the release.

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***When required to demonstrate product qualification, does the organization ensure that retained documented information provides evidence that the products and services meet the defined requirements? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Does the organization ensure that all documented information required to accompany the products and services are present at delivery? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8.7 Control of nonconforming outputs**

**8.7.1**

Does the organization ensure that outputs that do not conform to requirements are identified and controlled to prevent their unintended use or delivery?

Does the organization take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services, and does this also apply to nonconforming products and services detected after delivery of products, during or after the provision of services?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Is the nonconformity control process maintained as documented information including the provisions for:***

* ***defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;***
* ***taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;***
* ***timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;***
* ***defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2)? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization deal with nonconforming outputs in one or more of the following ways:

1. correction;
2. segregation, containment, return or suspension of provision of products and services;
3. informing the customer;
4. obtaining authorization for acceptance under concession ***by a relevant authority and, when applicable, by the customer? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Are dispositions of use-as-is or repair for the acceptance of nonconforming products implemented only:***

* ***after approval by an authorized representative of the organization responsible for design or by persons having delegated authority from the design organization;***
* ***after authorization by the customer, if the nonconformity results in a departure from the contract requirements? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Is product dispositioned for scrap conspicuously and permanently marked, or positively controlled, until physically rendered unusable? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Are counterfeit, or suspect counterfeit, parts controlled to prevent reentry into the supply chain? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Is conformity to requirements verified when nonconforming outputs are corrected?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8.7.2**

Is documented information retained that:

1. describes the nonconformity;
2. describes the actions taken;
3. describes any concessions obtained;
4. identifies the authority deciding the action in respect of the nonconformity?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**9 Performance evaluation**

**9.1 Monitoring, measurement, analysis and evaluation**

**9.1.1 General**

Does the organization determine:

1. what needs to be monitored and measured;
2. the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
3. when the monitoring and measuring must be performed;
4. when the results from monitoring and measurement are to be analyzed and evaluated?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Does the organization evaluate the performance and the effectiveness of the quality management system and retain appropriate documented information as evidence of the results?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**9.1.2 Customer satisfaction**

Does the organization monitor customer perceptions of the degree to which their needs and expectations have been fulfilled?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Has the organization determined the methods for obtaining, monitoring and reviewing this information?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Does information to be monitored and used for the evaluation of customer satisfaction include, but not limited to, product and service conformity, on-time delivery performance, customer complaints, and corrective action requests? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Are plans developed and implemented for customer satisfaction improvement that address deficiencies identified by these evaluations, and is effectiveness of the results assessed? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**9.1.3 Analysis and evaluation**

Does the organization analyze and evaluate appropriate data and information arising from monitoring and measurement, and are the results of analysis used to evaluate:

1. conformity of products and services;
2. the degree of customer satisfaction;
3. the performance and effectiveness of the quality management system;
4. if planning has been implemented effectively;
5. the effectiveness of actions taken to address risks and opportunities;
6. the performance of external providers;
7. the need for improvements to the quality management system?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**9.2 Internal audit**

**9.2.1**

Are internal audits conducted at planned intervals to provide information on whether the quality management system:

1. conforms to:
2. the organization’s own requirements for its quality management system;

2) the requirements of ISO 9001:2015;

1. is effectively implemented and maintained?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**9.2.2**

Does the organization:

1. plan, establish, implement and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements and reporting, which take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
2. define the audit criteria and scope for each audit;
3. select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
4. ensure that the results of the audits are reported to relevant management;
5. take appropriate correction and corrective actions without undue delay;
6. retain documented information as evidence of the implementation of the audit program and the audit results?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**9.3 Management review**

**9.3.1 General**

Does top management review the quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**9.3.2 Management review inputs**

Is the management review planned and carried out, taking into consideration:

1. the status of actions from previous management reviews;
2. changes in external and internal issues that are relevant to the quality management system;
3. information on the performance and effectiveness of the quality management system, including trends in:

1) customer satisfaction and feedback from relevant interested parties;

2) the extent to which quality objectives have been met;

3) process performance and conformity of products and services;

4) nonconformities and corrective actions;

5) monitoring and measurement results;

6) audit results;

7) the performance of external providers;

8) ***on-time delivery performance; (AS9100D)***

1. the adequacy of resources;
2. the effectiveness of actions taken to address risks and opportunities (see 6.1);
3. opportunities for improvement?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**9.3.3 Management review outputs**

Do the outputs of the management review include decisions and actions related to:

1. opportunities for improvement;
2. any need for changes to the quality management system;
3. resource needs;
4. ***risks identified? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Is documented information retained as evidence of the results of management reviews?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**10 Improvement**

**10.1 General**

Does the organization determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction, including:

1. improving products and services to meet requirements as well as to address future needs and expectations;
2. correcting, preventing or reducing undesired effects;
3. improving the performance and effectiveness of the quality management system?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**10.2 Nonconformity and corrective action**

**10.2.1**

When a nonconformity occurs, including any arising from complaints, does the organization:

1. react to the nonconformity and, as applicable:

1) take action to control and correct it;

2) deal with the consequences;

1. evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

1) reviewing and analyzing the nonconformity;

2) determining the causes of the nonconformity; ***including, as applicable,***

***those related to human factors***; ***(AS9100D)***

3) determining if similar nonconformities exist, or could potentially occur;

1. implement any action needed;
2. review the effectiveness of any corrective action taken;
3. update risks and opportunities determined during planning, if necessary;
4. make changes to the quality management system, if necessary;
5. ***flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;***
6. ***take specific actions when timely and effective corrective actions are not achieved? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Are corrective actions appropriate to the effects of the nonconformities encountered?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Is documented information maintained that defines the nonconformity and corrective action management processes? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**10.2.2**

Is documented information retained as evidence of:

1. the nature of the nonconformities and any subsequent actions taken;
2. the results of any corrective action?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**10.3 Continual improvement**

Does the organization continually improve the suitability, adequacy and effectiveness of the quality management system?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Are the results of analysis and evaluation, and the outputs from management review, considered, to determine if there are needs or opportunities that must be addressed as part of continual improvement?

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Is the implementation of improvement activities monitored and effectiveness of the results evaluated? (AS9100D)***

**Yes/No Evidence \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**